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FALLS CHURCH, VA 22040-0747

EXAMINER

KRUSE, DAVID H

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/992,914
Filing Date: December 18, 1997
Appellant(s): WATANABE ET AL.

Mark J. Nuell
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 December 2006 appealing from the Office
action mailed 1 December 2005.

1
2 **(1) Real Party in Interest**

3 A statement identifying by name the real party in interest is contained in the brief.

4 **(2) Related Appeals and Interferences**

5 The examiner is not aware of any related appeals, interferences, or judicial
6 proceedings, which will directly affect or be directly affected by or have a bearing on the
7 Board's decision in the pending appeal.

8 **(3) Status of Claims**

9 The statement of the status of claims contained in the brief is correct.

10 The Examiner notes that claims 52 and 53 in Appendix A are identified as
11 "Currently Amended", said claims incorporate the amendments submitted in the
12 Response filed on 12 September 2005. The claims are correct.

13 **(4) Status of Amendments After Final**

14 No amendment after final has been filed.

15 **(5) Summary of Claimed Subject Matter**

16 The summary of claimed subject matter contained in the brief is correct.

17 **(6) Grounds of Rejection to be Reviewed on Appeal**

18 The appellant's statement of the grounds of rejection to be reviewed on appeal is
19 correct.

20 **WITHDRAWN REJECTIONS**

21 The following grounds of rejection are not presented for review on appeal
22 because they have been withdrawn by the examiner. The rejection of claims 46-51, 75

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1 and 76 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description
2 has been withdrawn.

3 **(7) Claims Appendix**

4 The copy of the appealed claims contained in the Appendix to the brief is correct.

5 **(8) Evidence Relied Upon**

6 Tables 1 and 3, which were presented attached to Appellant's paper of
7 November 15, 2004.

8 Table 2, presented attached to Appellants' paper of February 24, 2004.

9 Exhibit 1, explanation of various sequence analysis programs, attached to
10 Appellant's paper of November 15, 2004.

11 Exhibit 4, Lehle and Tanner, *Eur. J. Biochem.* 38:103-110 (1973), attached to
12 Appellant's paper of November 15, 2005.

13 Declaration of Akistu NAGASAWA, attached to Appellant's paper of September
14 12, 2005.

15 Richmond et al., *Plant Physiol.* 124:495-498 (2000), cited by the Examiner in
16 Office Action of March 11, 2005.

17 Duggleby, *Gene* 190:245-249 (1997), cited by the Examiner in Office Action of
18 March 11, 2005.

19 Peterbauer et al., *Planta* 215:839-846 (2002), cited by the Examiner in Office
20 Action of March 11, 2005.

21 Osumi et al, U.S. Patent 6,891,084 (NEW).

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1 A sequence alignment a soybean raffinose synthase enzyme of SEQ ID NO: 24
2 taught by Osumi *et al*, U.S. Patent 6,891,084 with Appellant's SEQ ID NO: 4 (NEW).

3 **(9) Grounds of Rejection**

4 Claims 46-51 stand rejected under 35 U.S.C. § 101 because the claimed
5 invention is not supported by either a substantial asserted utility or a well-established
6 utility.

7 Claims 52-74, 77 and 82-86 stand rejected under 35 U.S.C. § 112, first
8 paragraph, as failing to comply with the written description requirement.

9 Claims 46-77 and 78-86 stand rejected under 35 U.S.C. § 112, first paragraph,
10 because the specification, while being enabling for an isolated nucleic acid encoding the
11 amino acid sequence of SEQ ID NO: 2, a chimeric nucleic acid comprising said isolated
12 nucleic acid, a transformant comprising said chimeric nucleic acid, a plasmid comprising
13 said nucleic acid, a host organism either a microorganism or plant comprising said
14 plasmid and a method of metabolic modification of a plant comprising introducing said
15 isolated nucleic acid, does not reasonably provide enablement for an isolated nucleic
16 acid encoding the amino acid sequence of SEQ ID NO: 4, 6 or 8, or an isolated nucleic
17 acid that hybridizes with a complement to said isolated nucleic acid isolated from any
18 leguminous, lamiaceous or monocotyledonous plant.

19 Claims 46, 47, 52, 53, 55 and 59-77 and 78-86 stand provisionally rejected under
20 the judicially created doctrine of obviousness-type double patenting as being
21 unpatentable over claims 1-3, 16-23 and 28-30 of copending Application No.
22 09/301,766.

(10) Response to Argument

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

Claims 46-51 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

Appellant argues that the present specification expressly describes that the present invention is related to isolated nucleic acids encoding raffinose synthase enzymes (see, page 2, lines 18-20). The specification describes raffinose synthase enzymes as catalyzing the rate-limiting step in raffinose oligosaccharides, which oligosaccharides are important in the food value of plants. The specification explains that raffinose synthases are present in plants of widely divergent species and urges that manipulation of the raffinose content of a plant, by manipulation of the amount of raffinose synthase expressed in the plant, is useful for making plants more healthy as foods, referring to pages 1-2 of the specification. Appellant argues that the specification also alleges that this manipulation can be in the form of over-expression of a raffinose synthase enzyme, or by decreasing the expression of raffinose synthase using antisense technology or the like, referring to page 26, lines 4-17 (of the specification). Appellant further argues that the Examiner does not at all challenge this asserted utility of the invention, thus it must be accepted that the asserted utility of the invention is credible, substantial and specific, and that such is consistent with the present allowance of claims 3 and 46. Page 6, 1st and 2nd paragraphs of the Appeal Brief.

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1 These arguments are not found to be persuasive. The instant rejection is directed
2 to the utility of the specific species of claims 46-51. The utility of the allowed claims
3 directed to the species of SEQ ID NO: 1 encoding SEQ ID NO: 2, a broad bean
4 raffinose synthase, has been established. The amino acid sequences of SEQ ID NO: 6
5 and 8 are incomplete and do not teach a full-length protein, and hence are not
6 functional. SEQ ID NO: 6 is 586 amino acids in length and SEQ ID NO: 8 is only 271
7 amino acids in length. One skilled in the instant art would immediately recognize that
8 SEQ ID NO: 6 or 8 are too short to teach a complete, functional enzyme and would
9 immediately recognize that both amino acid sequences are missing the N-terminal
10 regions that would start with a methionine. The amino acid sequence of SEQ ID NO: 4,
11 encoded by SEQ ID NO: 3, is asserted to be a soybean raffinose synthase enzyme.
12 However, Appellant has provided no evidence of such a function, and Osumi *et al* (U.S.
13 Patent 6,891,084) teach a soybean raffinose synthase enzyme at SEQ ID NO: 24, (a
14 sequence alignment attached hereto) shows only 32.9% sequence identity at the amino
15 acid level to Appellant's SEQ ID NO: 4. Appellant's own arguments of record concerning
16 structure-function relationship among raffinose synthase enzymes that distinguish them
17 from stachyose synthase enzymes suggests that Appellant's SEQ ID NO: 4 does not
18 teach a raffinose synthase. The Nagasawa Declaration, filed under 37 CFR § 1.132 on
19 12 September 2005, states that the homologies between RFSs (Raffinose Synthases)
20 and SIP (Seed Imbibition Protein) are less than 40%. The Nagasawa Declaration states
21 that the homologies between RFSs and STSs (Stachyose Synthases) are not higher
22 than 45%. The Nagasawa Declaration states that on the other hand, the homologies

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1 among RFSs are all 50% or higher. The Nagasawa Declaration states that thus, the
2 homologies among RFSs are higher than those homologies between RFSs and SIP and
3 between RFSs and STSs (see page 7 of the Nagasawa Declaration). As a result, it is
4 apparent that the amino acid sequence of SEQ ID NO: 4 fails to teach a functional
5 raffinose synthase enzyme due to its low sequence identity of less than 50% to an
6 established soybean raffinose synthase enzyme. It is equally apparent that both SEQ ID
7 NOs 6 and 8 are too short and thus do not describe functional raffinose synthase
8 enzymes.

9 Appellant argues that the Examiner's position is incorrect and that the present
10 record contains sufficient evidence that one of ordinary skill in the art is able to
11 distinguish a RFS from a STS by analysis of the overall degree of amino acid sequence
12 similarity of any desired protein to the amino acid sequence of one of the SEQ ID NOs:
13 2, 4, 6 or 8 of the present application. Appellant further argues that the present claims
14 46-51 recite defined amino acid sequences of specific nucleotide sequences that are
15 one sequence that may encode the defined amino acid sequence. The nucleic acid
16 sequences are those of the raffinose synthase cDNAs cloned from soybean, Japanese
17 artichoke and corn, as in Examples 7, 9 and 11 of the specification; the amino acid
18 sequences are those obtained by translation of the cDNA sequences. Paragraph
19 spanning pages 6-7, and page 7, 2nd paragraph of the Appeal Brief.

20 These arguments are not found to be persuasive, and have been addressed
21 above. Specifically, the percent identity of the cited sequences does not meet the
22 standard set forth in Appellants won declaration (the Nagasawa Declaration).

1 Appellant argues that as to the "structure-function relationship" defining the
2 genus of the nucleic acids encoding a raffinose synthase, Appellant does not see how
3 this applies to the present claims 46-51 (because the claims are limited to particular
4 defined sequences). Appellant further argues that a distinct structure of a particular
5 amino acid sequence or of a particular nucleic acid sequence is recited in these claims.
6 Appellant further argues that the present specification, and the record of the present
7 application, makes clear that the question of utility before the Board relates to whether
8 the amino acid sequence of a particular protein is sufficient for determining whether or
9 not the protein would be more likely than not to possess raffinose synthase activity.
10 Appellant also argues there is substantial evidence of record that one of ordinary skill in
11 the art can distinguish a RFS enzyme from a STS enzyme solely on the basis of amino
12 acid sequence. Appellant argues that Appellant has previously provided phylogenetic
13 analyses of the amino acid sequence of RFSs and STSs and has established that the
14 degree of sequence homology among RFSs and among STSs is significantly higher
15 than the degree of homology between RFSs and STSs. This relationship is robust to
16 analysis using two different sequence identity determination algorithms. See, Table 3
17 attached to the Amendment filed November 15, 2004 and Table 2 attached to the
18 Amendment filed February 25, 2004, both presented in Evidence Appendix B. To this
19 evidence, Appellant has added the Declaration of Mr. Akitsu Nagasawa also provided in
20 Evidence Appendix B. Mr. Nagasawa attests to the methodology used to generate the
21 data in Tables 2 and 3 and presents an additional analysis using yet a third approach to
22 calculating sequence identity. See page 7, 3rd and 4th paragraphs of the Appeal Brief.

1 Appellant additionally argues that the argument of the Examiner is not
2 persuasive, not the least because it ignores that the present specification includes a
3 second amino acid sequence, SEQ ID NO: 2, demonstrated to exhibit raffinose
4 synthase activity and three additional sequences that are compared to that sequence.
5 Appellant's argument is that the sequences independently described by the
6 specification are identifiable as a group separate from sequences that form another
7 group of sequences, which happen to be stachyose synthases (or from a second group
8 of SIPs, see the Declaration of Mr. Nagasawa). See page 8, 4th paragraph of the
9 Appeal Brief.

10 These arguments are not found to be persuasive. The issue concerning amino
11 acid sequences of SEQ ID NO: 6 and 8, i.e. that the sequences are incomplete is
12 outlined above. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic
13 *quid pro quo* contemplated by the Constitution and the Congress for granting a patent
14 monopoly is the benefit derived by the public from an invention with substantial utility.
15 Unless and until a process is refined and developed to this point--where specific benefit
16 exists in currently available form--there is insufficient justification for permitting an
17 applicant to engross what may prove to be a broad field." As for SEQ ID NO: 4 (instant
18 claims 46 and 47) Appellant's assertion is based on facts that were not known until after
19 the filing of the instant Application. In Table 1 of The Nagasawa Declaration, six (6)
20 proteins are listed as raffinose synthases, Sc-02 and Sc-04 being taught in the instant
21 application, and Aj-05 being the cucumber raffinose synthase of the prior art
22 acknowledged in the Information Disclosure Statement filed on 5 March 2001. The

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1 proteins Sc-03 and Sc-05 are taught in a related application assigned to the Appellant,
2 which has a foreign priority of 30 April 1998, and the PsRFS (pea Raffinose Synthase)
3 was taught by Peterbauer *et al* in 2002. Given the U.S. filing date of 18 December 1997
4 of the instant application, only two complete and confirmed raffinose synthase enzyme
5 amino acid sequences, and one being the asserted raffinose synthase of SEQ ID NO: 4,
6 were known in the art at the time of the instant invention. The Examiner has established
7 the fact that at the time of the instant invention, only one other plant raffinose synthase
8 "gene" was known in the art, that being from cucumber and disclosed in US Patent
9 6,166,292 (see Office action mailed 6 February 2002, page 5). It is unclear how
10 Appellant at the time of filing could make an assumption of function of an encoded
11 "enzyme" using sequence similarity without actually showing the expressed encoding
12 nucleic acid actually produced a raffinose synthase at the time of the instant invention
13 (page 3 of the Office action mailed on 1 December 2005). The Examiner's argument is
14 based on the fact that it appears that only one of Appellant's amino acid sequences is
15 actually a raffinose synthase (SEQ ID NO: 2), and thus Appellant's assertion of a
16 structural-functional relationship is based on the comparison of only two amino acid
17 sequences.

18 ***Claim Rejections - 35 USC § 112, Written Description***

19 Claims 52-74, 77 and 82-86 stand rejected under 35 U.S.C. § 112, first
20 paragraph, as failing to comply with the written description requirement.

21 As stated above, the rejection of claims 46-51, 75 and 76 under 35 U.S.C. § 112,
22 first paragraph, for lack of adequate written description has been withdrawn. As this

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1 rejection is no longer directed to claims 46-51, Appellant's arguments are moot, as they
2 relate to these claims. The instant rejection, as directed to claims 52-74, 77 and 82-86 is
3 maintained.

4 Appellants argue that the claims are directed to nucleic acids "comprising" the
5 sequences 5 and 7, encoding the partial RFS proteins of SEQ ID NOs: 6 and 8.

6 Nonetheless, these sequences must be taken as described to this extent. Appellant
7 states that the working Examples 5-11 of the specification provide description of the
8 experiments in which the cDNAs encoding raffinose synthases from broad bean,
9 soybean, Japanese artichoke and corn are obtained. Appellant further argues that the
10 experiments of Examples 5-9 are described in a manner that indicates that the full-
11 length cDNA is cloned, and thus the coding portion from amino terminal to carboxy-
12 terminal of the raffinose synthase protein is obtained. See, e.g. Example 6 at page 32,
13 in which use of data from the 5' end of a first cDNA clone are used to construct a primer
14 for extending the cDNA at least to the end of the coding portion of the corresponding
15 mRNA. Appellant additionally argues that the amino acid sequence set forth in SEQ ID
16 NO: 4 is complete, and SEQ ID NOs: 6 and 8 are partial protein sequences, but
17 sufficiently long to allow determination that they encode a RFS, or at least part of one,
18 by their degree of overall identity to the known RFS of SEQ ID NO: 2. See page 11, 1st
19 and 2nd paragraph of the Appeal Brief.

20 These arguments are not found to be persuasive. As pointed out above, Osumi
21 *et al* (U.S. Patent 6,891,084) teach a soybean raffinose synthase enzyme at SEQ ID
22 NO: 24, (a sequence alignment attached hereto) that shows only 32.9% sequence

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1 identity at the amino acid level with Appellant's SEQ ID NO: 4. Appellant's own
2 arguments of record concerning structure-function relationship among raffinose
3 synthase enzymes that distinguish them from stachyose synthase enzymes would
4 suggest that Appellant's SEQ ID NO: 4 does not teach a raffinose synthase due to its
5 low sequence identity. See the Nagasawa Declaration filed under 37 CFR § 1.132 on 12
6 September 2005, page 7. As directed to the partial sequences of SEQ ID NOs: 6 and 8,
7 these sequences fail to adequately describe an isolated nucleic acid encoding a
8 raffinose synthase enzyme. The amino acid sequences of SEQ ID NO: 6 and 8 are
9 incomplete and do not describe a full-length protein, and hence are not functional. SEQ
10 ID NO: 6 is 586 amino acids in length and SEQ ID NO: 8 is only 271 amino acids in
11 length. One skilled in the instant art would immediately recognize that SEQ ID NO: 6 or
12 8 are too short to describe a complete, functional enzyme and would immediately
13 recognize that both amino acid sequences are at least missing the N-terminal regions
14 that would start with a methionine. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004),
15 at 1940: Claims in application directed to isolated DNA molecules encoding proteins
16 that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to
17 satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed
18 nucleic acids encoding protein for which they provided only partial sequence, and
19 without approximately 95 percent of amino acid sequence that applicants did not
20 disclose, it cannot be held that DNA molecules claimed in application have been
21 described, since applicants' contention that they were in physical possession of protein
22 does not establish their knowledge of that protein's amino acid sequence or any of its

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1 other descriptive properties, even though amino acid sequence is inherent property of
2 protein, and since application does not provide adequate functional description, in that,
3 with only partial amino acid sequence disclosed, chemical structure of nucleic acid
4 molecules that can serve function of encoding protein's amino acid sequence cannot be
5 determined. Appellant has not established the function of the amino acid sequences of
6 SEQ ID NO: 6 or 8. The Examiner notes that claims 53-58, 61, 62, 64, 66, 70-72, 74
7 and 77 are directed to isolated nucleic acids and compositions comprising isolated
8 nucleic acids from laminaceous and monocotyledonous plants encoding raffinose
9 synthase only described by a possible method of making, wherein Applicants have not
10 adequately described a single species of the genus claimed.

11 Appellant argues that Appellant's burden is to establish, by a preponderance of
12 the evidence, that the amino acid sequences of SEQ ID NOs: 4, 6 and 8 represent
13 proteins having raffinose synthase activity. *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed.
14 Cir. 1992). Appellant further argues that the particular amino acid sequences in question
15 were obtained by a cloning method generally accepted in the art as useful for cloning
16 functionally homologous proteins across species lines. Comparison of the full-lengths of
17 these sequences against SEQ ID NO: 2, known to encode a raffinose synthase, shows
18 that they have a degree of sequence identity accepted by one of ordinary skill in the art
19 to establish that they are likely to be raffinose synthase enzymes, as opposed to
20 stachyose synthases or seed imbibition proteins. This conclusion is supported by the
21 Declaration testimony of Mr. Nagasawa and furthermore, Mr. Nagasawa's method of
22 analysis has been shown to be robust to the application of three different computational

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1 methods. Against this evidence, the Examiner has raised only his opinion supported by
2 an analysis that is incomplete. Page 12, 2nd paragraph of the Appeal Brief.

3 Appellant argues that it is entirely proper to claim an invention in product-by-
4 process terms, *Fiers v. Revel*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). Appellant
5 further argues that claims 53-58 in effect describe the working examples of the
6 specification, which represent an actual reduction to practice of four different species of
7 the invention. Appellant additionally argues that therefore, it must be accepted that the
8 process described in claims 53-58 is effective for obtaining operable embodiments of
9 the invention. Page 13, 3rd paragraph of the Appeal Brief.

10 This argument is not found to be persuasive. Appellant has not provided a
11 preponderance of evidence indicating that the amino acid sequences have raffinose
12 synthase activity. The Examiner has established that at the time of the instant invention,
13 one skilled in the art would have required evidence of specific function for a putative
14 raffinose synthase because of the similarity to both stachyose synthases and seed
15 imbibition proteins. The issue of whether it is proper to claim an invention in product-by-
16 process terms is irrelevant to the instant rejection. The issue is whether Appellant was
17 in possession of the invention as broadly claimed. The process of making must
18 adequately describe the process made in order to adequately describe the product. See
19 *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which
20 teaches that the disclosure of a process for obtaining cDNA from a particular organism
21 and the description of the encoded protein fail to provide an adequate written
22 description of the actual cDNA from that organism which would encode the protein from

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1 that organism, despite the disclosure of a cDNA encoding that protein from another
2 organism. At 1406, the court states that a description of a genus of cDNAs may be
3 achieved by means of a recitation of a representative number of cDNAs, defined by
4 nucleotide sequence, falling within the scope of the genus or of a recitation of structural
5 features common to the members of the genus, which features constitute a substantial
6 portion of the genus. Appellant has not recited structural features common to the genus
7 of raffinose synthases. Their sole evidence lies with the purported assertion of
8 sequence similarity, which is flawed as discussed above.

9 Appellant argues that contrary to the Examiner's assertion that the claims
10 (specifically, claims 53-58) do not include any correlation between structure and
11 function, the claims include two structural features that are connected to operable
12 embodiments. First, there are the primer sequences utilized in the process. Appellant
13 argues that these primers represent portions of the raffinose synthase cDNAs of the
14 family of plants recited that are conserved among the raffinose synthases from that
15 family, as evidenced by their successful use in isolating cDNAs encoding raffinose
16 synthases from plants of those families. Appellant further argues that the primer
17 sequences are incorporated into the product nucleic acid, and so represent at least a
18 minimal specific sequence in the product. Appellant also argues that the claims recite
19 that the nucleic acid obtained as the amplification product must hybridize to a nucleic
20 acid that is known to encode a raffinose synthase under conditions accepted in the art
21 to constrain the hybridizing sequence to those having a high degree of sequence
22 identity. Paragraph spanning pages 13-14 of the Appeal Brief.

1 Appellant argues that because claims 53-58 include structural features correlated
2 with function of the obtained nucleic acid as a raffinose synthase, and because the
3 working examples of the specification demonstrate actual reduction to practice of the
4 invention as set forth in claims 53-58, Appellant submits that these claims are well-
5 supported by the specification. Accordingly, the rejection of claims 53-58 under 35
6 U.S.C. § 112, first paragraph, for alleged lack of written description support in the
7 specification, should be reversed. See page 14, 3rd paragraph of the Appeal Brief.

8 These arguments are not found to be persuasive. No specific sequences are
9 claimed and Appellant has failed to describe the genus of leguminous, laminaceous or a
10 monocotyledonous plant raffinose synthase encoding nucleic acids as broadly claimed.
11 There are about 65,000 monocot species known world wide, and the Leguminosae has
12 between 16,000 to 19,000 species. One skilled in the art would not have recognized
13 that Appellant was in possession of such a genus of nucleic acids isolated from a plant
14 as broadly claimed. As stated above, *University of California V. Eli Lilly and Co.*, 43
15 USPQ2d 1398 (Fed. Cir. 1997), teaches that the disclosure of a process for obtaining
16 cDNA from a particular organism and the description of the encoded protein fail to
17 provide an adequate written description of the actual cDNA from that organism which
18 would encode the protein from that organism, despite the disclosure of a cDNA
19 encoding that protein from another organism. Leguminous, laminaceous and
20 monocotyledonous plants encompass a vast number of species to which the instant
21 claims are directed.

1 Appellant argues that the Examiner has not set forth any particular explanation of
2 any separate grounds of rejection other than those explained above, and therefore the
3 various arguments applied to claims 52 or 53, as may be applicable, should be applied
4 to these claims as well, and that the Board should consider that the plasmid aspect of
5 claims 65 and 66 is thus deemed well described by the specification and the instant
6 rejection should be reversed as to claims 65 and 66. Page 15, 2nd paragraph of the
7 Appeal Brief. Appellant argues that the Board should consider that the promoter aspect
8 of claims 59-62 is thus deemed well-described by the specification and the instant
9 rejection should be reversed as to claims 59-62. See the paragraph spanning pages 14-
10 15 of the Appeal Brief. Appellant further argues and that the Board should consider that
11 the transformant and host organism aspects of claims 63, 64 and 67-72 are thus
12 deemed well described by the specification and the instant rejection should be reversed
13 as to claims 63, 64 and 67-72. See page 15, 3rd paragraph of the Appeal Brief.
14 Appellant additionally argues that the Board should consider that the metabolic
15 transformation aspect of claim 73 is thus deemed well described by the specification
16 and the instant rejection should be reversed as to claim 73. See the paragraph
17 spanning pages 15-16 of the Appeal Brief. Additionally, Appellant states that the Board
18 should consider that the metabolic transformation aspect of claim 74 is thus deemed
19 well-described by the specification and the instant rejection should be reversed as to
20 claim 74. See page 16, 2nd paragraph of the Appeal Brief.

21 Appellant argues that claim 77 represents a subgenus compared to claim 53, in
22 that the plant from which the template nucleic acid obtained is more specifically defined

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1 to the level of a species. Appellant further argues that compared to claim 53, claim 77
2 more closely describes the working examples 5-11, and so to that degree must be
3 acknowledged to be well-described by the specification. See page 16, 4th paragraph of
4 the Appeal Brief.

5 Appellant argues that the relatively high degree of identity between SEQ ID NOs:
6 2 and 4 very clearly establishes that SEQ ID NO: 3 encodes a RFS protein, rather than
7 a STS or SIP. Appellant further argues that these are the sequences that are "full-
8 length" and demonstrated to or thus very likely to represent an active enzyme (or
9 encode one), accordingly the subject matter of claims 84 and 85 must be deemed well
10 described by the present specification. See page 18, 1st paragraph of the Appeal Brief.

11 Appellant argues that the relatively high degree of identity between SEQ ID NOs: 2 and
12 4 very clearly establishes that SEQ ID NO: 3 encodes a RFS protein, rather than a STS
13 or SIP. Appellant argues that furthermore, these are the sequences that are "full-length"
14 and are either demonstrated to are very likely to represent an active enzyme (or encode
15 one). Accordingly the subject matter of claim 86 must be deemed well described by the
16 present specification. See page 18, 2nd paragraph of the Appeal Brief.

17 These arguments are not found to be persuasive. Because the claimed chimeric
18 gene comprises the isolated nucleic acid of claims 52-58, hence claims 59-62 lack
19 adequate written description for the same reasons. In the same manner, the plasmid of
20 claims 65 and 66, the transformant and host organism of claims 63, 64 and 67-72, and
21 the metabolic transformation aspect of claim 73 or 74 lack adequate written description
22 because they comprise nucleic acids that have not been adequately described. The

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1 Examiner has not argued that the promoter aspect lacks adequate written description,
2 just the nucleotide sequence coding for an amino acid sequence of a raffinose synthase
3 as broadly claimed lacks adequate written description.

4 ***Claim Rejections - 35 USC § 112, Scope of Enablement***

5 Claims 46-77 and 78-86 stand rejected under 35 U.S.C. § 112, first paragraph,
6 because the specification, while being enabling for an isolated nucleic acid encoding the
7 amino acid sequence of SEQ ID NO: 2, a chimeric nucleic acid comprising said isolated
8 nucleic acid, a transformant comprising said chimeric nucleic acid, a plasmid comprising
9 said nucleic acid, a host organism either a microorganism or plant comprising said
10 plasmid, and a method of metabolic modification of a plant comprising introducing said
11 isolated nucleic acid, does not reasonably provide enablement for an isolated nucleic
12 acid encoding the amino acid sequence of SEQ ID NO: 4, 6 or 8, or an isolated nucleic
13 acid that hybridizes with a complement to said isolated nucleic acid isolated from any
14 leguminous, laminaceous or monocotyledonous plant.

15 Appellant argues that the Examiner has only addressed the predictability in the
16 art, in the sense that his position is that, because the specification only actually
17 demonstrates biological activity as a raffinose synthase for SEQ ID NO: 2, and the
18 degree of sequence identity among the amino acid sequences identified in the working
19 examples is as low as 60%, [and that] Appellant cannot reliably assign the biochemical
20 activity of a raffinose synthase to the amino acid sequences of SEQ ID NOs: 4, 6 and 8.
21 To the degree that the Examiner has addressed the other factors to be considered at

1 all, it is only to describe his disagreement with positions on these issues expressed by
2 Appellant. See page 20, 1st paragraph of the Appeal Brief.

3 Appellant argues that the skilled artisan can follow detailed teachings in the
4 specification of how to clone, express and evaluate DNAs that are likely to encode
5 functional raffinose synthase enzymes. Appellant argues that it is true that it is
6 unpredictable whether any individual clone made in an experiment will include a DNA
7 encoding a functional enzyme, but it is not unpredictable whether the skilled artisan
8 would succeed in identifying at least one functional DNA in an experiment as a whole, to
9 the contrary, it is very likely that the skilled artisan would find a cloned DNA encoding a
10 functional enzyme by following the teachings of the specification. See page 23, 4th
11 paragraph of the Appeal Brief.

12 These arguments are not found to be persuasive. As directed to claims 46-51,
13 since the claimed invention is not supported by either a substantial asserted utility or a
14 well established utility for the reasons set forth on the record, one skilled in the art
15 clearly would not know how to use the claimed invention. The Examiner has addressed,
16 by the nature of the rejection, the breadth of the claims, the nature of the invention, and
17 the state of the prior art, and additionally addressed the predictability of the art at the
18 time of the invention. All of these factors were considered as they relate to isolation of
19 nucleic acids encoding plant raffinose synthase enzymes. The Examiner has provided
20 evidence that one of skill in the instant art would require more than sequence similarity
21 as evidence of function, contrary to Appellant's assertion. See Duggleby 1997 and
22 Richmond *et al* 2000, Plant Physiology 124: 495-498, at the paragraph spanning left

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1 and right column on page 497 (previously cited). The number of species of isolated
2 nucleic acids within the scope of the claims would have required undue trial and error
3 experimentation to make and use. There are about 65,000 monocot species known
4 world wide, and the Leguminosae has between 16,000 to 19,000 species. Given the
5 vast breadth of instant claim 52, for example, it would have required undue trial and
6 error experimentation to make and use the invention as broadly claimed.

7 Appellant argues that the Examiner's analysis of the question of undue
8 experimentation looks only at the factor of whether working examples of the claimed
9 invention are described in the specification and an assertion that it is unpredictable that
10 a particular nucleic acid produced according to the teachings of the invention would in
11 fact exhibit raffinose synthase activity. Appellant further argues that this analysis is
12 legally insufficient to establish a *prima facie* lack of enablement, as the Examiner fails to
13 consider the breadth of the claims, the nature of the invention, the level of ordinary skill
14 in the art, the quantity of the experimentation needed, the guidance provided by the
15 specification (other than the presence or absence of working examples) and the state of
16 the art at the time the invention was made. Furthermore, Appellant argues that the kind
17 of predictability, a prior knowledge of functionality of the enzyme obtained using the
18 methods of the invention, is not the kind of predictability envisioned by the Court in
19 *Wands*. See page 21, 2nd paragraph of the Appeal Brief.

20 Appellant argues that the art of molecular biology, in particular the art of
21 expression of recombinant proteins, is one in which the artisan of ordinary skill expects
22 to perform a few weeks or months of experimentation in generating variants of a protein,

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1 then isolating clones encoding those variants and then (perhaps) re-cloning the isolated
2 variants into vectors for expressing a protein, and then screening expressed proteins for
3 activity. See page 21, 4th paragraph of the Appeal Brief.

4 Appellant argues that the artisan of ordinary skill in the art of cloning and
5 expressing recombinant proteins is generally accepted as one having a PhD. degree
6 and perhaps higher. Such a person is skilled in the design and performing of
7 experiments for isolating DNA clones and for screening them for a desired property, for
8 example encoding a protein having a particular activity. See page 21, 5th paragraph of
9 the Appeal Brief.

10 Appellant argues that the amount of experimentation needed to practice the
11 present invention is not unduly large or burdensome. Appellant additionally argues that
12 the practitioner must isolate a template genomic DNA from an organism, perform a
13 polymerase chain reaction using primers described in the specification to generate an
14 amplified fragment, clone that fragment into an expression vector, express the encoded
15 protein and then screen the protein for activity as a raffinose synthase. All of these
16 steps are either well-known in the art or described in detail in the specification and
17 furthermore are expected to be performed by the artisan of ordinary skill. Appellant
18 argues that at the time the invention was made, the state of the art of molecular biology
19 was such that the various laboratory operations that must be performed to carry out the
20 experimentation required to practice the instant invention, i.e. cloning of DNA molecules
21 and expressing them in a host cell, were routine. Also, polymerase chain reaction
22 amplification of nucleic acids was routine. The raffinose content of a number of

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1 organisms, especially including plants and some algae, was known. The biochemistry of
2 raffinose synthesis in plants had been established, and the role of raffinose synthases
3 as rate-limiting of raffinose production was known. See page 22, 1st to 3rd paragraphs of
4 the Appeal Brief.

5 These arguments are not found to be persuasive. The *Wands* factors put forth by
6 the Court takes into consideration the general skill of one in the art at the time of the
7 invention. The Examiner has provided evidence that one of skill in the instant art would
8 require more than sequence similarity as evidence of function, contrary to Appellant's
9 assertion. The art teaches that raffinose synthase enzymes have high overall amino
10 acid sequence homology with seed imbibition proteins and stachyose synthases, hence
11 amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al*
12 2002, *Planta* 215: 839-846, see page 840, left column and page 841, right column;
13 previously cited). Given the breadth of the claimed invention, for example claim 53
14 directed to nucleic acids encoding a raffinose synthase enzyme isolated from any
15 leguminous, laminaceous, or monocotyledonous plant using specific primers, and the
16 number of species that fall within these groups of plants, it would have required undue
17 trial and error experimentation at the time of the instant invention to screen and confirm
18 the function of such a broad genus of isolated nucleic acids as claimed. Additionally, it is
19 unclear from the instant specification that the recited primers would actually identify a
20 raffinose synthase encoding nucleic acid from a plant species other than that of the
21 homologous plant, if in fact the taught nucleic acid from which the primers were
22 produced actually encodes a raffinose synthase enzyme which has been brought into

1 question above. The instant application provided no guidance on how to distinguish
2 isolated nucleic acids encoding raffinose synthase from those encoding stachyose
3 synthase. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That
4 paragraph (35 USC 112, first) requires that the scope of the claims must bear a
5 reasonable correlation to the scope of enablement provided by the specification to
6 persons of ordinary skill in the art. In cases involving predictable factors, such as
7 mechanical or electrical elements, a single embodiment provides broad enablement in
8 the sense that, once imagined, other embodiments can be made without difficulty and
9 their performance characteristics predicted by resort to known scientific laws. In cases
10 involving unpredictable factors, such as most chemical reactions and physiological
11 activity, the scope of enablement obviously varies inversely with the degree of
12 unpredictability of the factors involved."

13 Appellant argues that the specification provides ample guidance to the skilled
14 artisan for practicing the invention broadly. In particular, the specification discloses in
15 detail how to clone DNAs encoding putative raffinose synthase enzymes. Appellant
16 further argues that the specification provides details such as organisms likely to be
17 useful for isolating template genomic DNA or cDNA (see, e.g. page 1, lines 9-14) and
18 methods for cloning DNA encoding a putative raffinose synthase enzyme from an RNA
19 fraction, including an extensive list of primers that can be utilized for PCR amplification
20 from templates obtained from different organisms (see, e.g. page 10, line 11 to page 18,
21 line 14). Appellant additionally argues that the specification describes methods for
22 expressing the cloned DNA in plant cells and in bacteria (see, e.g. page 24, line 3 to

1 page 27, line 23) and an example of expression in bacteria (Example 8 beginning at
2 page 39). Additionally Appellant argues that the specification describes how to purify
3 raffinose synthase from plant cells (see, e.g. Example 3 beginning on page 32). As a
4 result, the specification describes a biochemical assay for raffinose synthase, referring
5 to the Lehle article noted above and summarizing the procedure in Example 2 beginning
6 at page 31. The specification also provides a number of working examples of isolation
7 of partial or complete raffinose synthase genes from a number of different plants. See
8 Examples 7 and 9 to 11 and of transformation of a plant (soybean) with a cloned DNA
9 encoding a raffinose synthase (Example 13). See the section spanning pages 22-23 of
10 the Appeal Brief.

11 Appellant argues that applicants have provided evidence to support an assertion
12 that one of ordinary skill in the art can readily distinguish a RFS from a STS or a SIP.
13 The Nagasawa Declaration demonstrates unequivocally that the RFS subfamily of
14 glycoside hydrolases (see Appellants' discussion of Peterbauer *et al*, below) is easily
15 distinguished from the STS or SIP subfamilies of glycoside hydrolases on the basis that
16 RFSs are more similar to each other, and STSs are more similar to each other, than
17 RFSs are similar to STSs. Appellant argues that this relationship among their amino
18 acid sequences can be used to construct a "molecular phylogenetic tree" upon a branch
19 of which any particular amino acid sequence thought to represent a RFS or STS (or
20 SIP) can be placed. Appellant further argues that the Nagasawa Declaration additionally
21 explains that this analysis is robust in its conclusions (though perhaps the specific

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1 degrees of sequence similarity may vary) to three different approaches to sequence
2 similarity analysis. See the paragraph spanning pages 23-24 of the Appeal Brief.

3 These arguments are not found to be persuasive. The instant application only
4 provides guidance on how to make and use one species of raffinose synthase encoding
5 nucleic acid, that being a nucleic acid encoding SEQ ID NO: 2, a broad bean raffinose
6 synthase. The Examiner has established that those skilled in the instant art recognize
7 that cloning DNA is routine, but determining what the cloned DNA encodes requires
8 additional steps, and that one of skill in the art cannot presume encoded function simply
9 based on sequence similarity. As pointed out previously, Osumi *et al* (U.S. Patent
10 6,891,084) teach a soybean raffinose synthase enzyme at SEQ ID NO: 24, [a sequence
11 alignment attached hereto) shows only 32.9% sequence identity at the amino acid level
12 with Appellant's SEQ ID NO: 4. Appellant's own arguments of record concerning
13 structure-function relationship among raffinose synthase enzymes that distinguish them
14 from stachyose synthase enzymes would suggest that Appellant's SEQ ID NO: 4 does
15 not teach a raffinose synthase. See the Nagasawa Declaration filed under 37 CFR §
16 1.132 on 12 September 2005, page 7. In Table 1 of The Nagasawa Declaration, six (6)
17 proteins are listed as raffinose synthase, Sc-02 and Sc-04 being taught in the instant
18 application, and Aj-05 being the cucumber raffinose synthase of the prior art
19 acknowledged in the Information Disclosure Statement filed on 5 March 2001. Sc-03
20 and Sc-05 are taught in a related application assigned to the Appellant, which has a
21 foreign priority of 30 April 1998, and PsRFS (pea raffinose synthase) was taught by
22 Peterbauer *et al* in 2002. Given the U.S. filing date of 18 December 1997 of the instant

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1 application, only two complete and confirmed raffinose synthase enzyme amino acid
2 sequences, one being the asserted raffinose synthase of SEQ ID NO: 4, were known in
3 the art at the time of the instant invention. The Examiner has established the fact that at
4 the time of the instant invention, only one other plant raffinose synthase "gene" was
5 known in the art, that being from cucumber and disclosed in US Patent 6,166,292 (see
6 Office action mailed 6 February 2002, page 5). It is unclear how Appellant at the time of
7 filing could make an assumption of function of an encoded "enzyme" using sequence
8 similarity without actually showing the expressed encoding nucleic acid actually
9 produced a raffinose synthase at the time of the instant invention.

10 Appellant argues that claims 59-62 relate to chimeric genes comprising the
11 isolated nucleic acids described in claims 6, 43 and 48-53, operatively linked to a
12 promoter. Appellant asserts that the Examiner has not set forth any particular
13 explanation of any separate reason for lack of enablement other than those explained
14 above, and therefore the various arguments applied to claims 46-53, as may be
15 applicable, should be applied to these claims as well. See page 26, 4th paragraph of the
16 Appeal Brief.

17 Appellant argues that claims 65 and 66 relate to plasmids comprising the isolated
18 nucleic acids described in claims 6, 43 and 46-53. Appellant argues that claims 63, 64
19 and 67-72 relate to transformants and host organisms transformed with chimeric genes
20 or plasmids described in claims 59-63 or 65-66 (see page 27, 2nd paragraph of the
21 Appeal Brief). Appellant argues that claim 73 is directed to a method for metabolic
22 modification of a plant using the cloned DNA described in claim 52 (see page 27, 3rd

1 paragraph of the Appeal Brief). Appellant argues that claim 74 is directed to a method
2 for metabolic modification of a plant using the cloned DNA described in claim 53 (see
3 page 28, 1st paragraph of the Appeal Brief). Appellant asserts that the Examiner has not
4 set forth any particular explanation of any separate reason for lack of enablement other
5 than those explained above, and therefore the various arguments applied to claims 46-
6 53, as may be applicable, should be applied to these claims as well. See page 27, 1st
7 paragraph of the Appeal Brief.

8 Appellant argues that claim 78 is directed to isolated nucleic acids within claim 52
9 encoding either the amino acid sequence of SEQ ID NO: 2, which is demonstrated to
10 have RFS activity, or SEQ ID NO: 4, a full length protein sequence having 75% identity
11 to SEQ ID NO: 2 and thus very likely to demonstrate RFS activity. Thus, the breadth of
12 claim 78 encompasses fewer embodiments compared to the scope of claim 52 and the
13 predictability of the art is somewhat higher. Appellant further argues that the amount of
14 experimentation needed to test operability of a protein of amino acid sequence of SEQ
15 ID NO: 4 is very small and such experimentation is very well guided by the specification;
16 e.g. the nucleic acid encoding this amino acid sequence can be substituted for that
17 encoding SEQ ID NO: 2 as described by the working example 8. See page 28, 2nd
18 paragraph of the Appeal Brief.

19 These arguments are not found to be persuasive. The Examiner has brought into
20 question whether the specification teaches one of skill in the art how to use a nucleotide
21 sequence encoding the amino acid sequence of SEQ ID NO: 4 using the guidance of
22 the specification without knowing what function the amino acid sequence has.

1 Appellant argues that claims 79 and 80 are directed to the subset of the chimeric
2 genes of claims 59 and 65 in which the portion encoding an amino acid sequence
3 encodes either the amino acid sequence of SEQ ID NO: 2, which is demonstrated to
4 have RFS activity, or SEQ ID NO: 4, a full length protein sequence having 75% identity
5 to SEQ ID NO: 2 and thus very likely to demonstrate RFS activity. Appellant further
6 argues that the breadth of claims 79 and 80 encompass fewer embodiments compared
7 to the scope of claims 59 and 65, and the predictability of the art is somewhat higher,
8 and that the amount of experimentation needed to test operability of a protein of amino
9 acid sequence of SEQ ID NO: 4 is very small and such experimentation is very well
10 guided by the specification; e.g. the nucleic acid encoding this amino acid sequence can
11 be substituted for that encoding SEQ ID NO: 2 as described by the working example 8.
12 See the paragraph spanning pages 28-29 and page 29, 2nd paragraph of the Appeal
13 Brief.

14 Appellant argues that claim 81 is directed to methods for metabolic modification
15 of a host organism utilizing a subset of the nucleic acids within the scope of claim 73 in
16 which the nucleotide sequence encodes either the amino acid sequence of SEQ ID NO:
17 2, which is demonstrated to have RFS activity, or SEQ ID NO: 4, a full length protein
18 sequence having 75% identity to SEQ ID NO: 2 and thus very likely to demonstrate RFS
19 activity. Appellant argues that the breadth of claim 81 encompasses fewer embodiments
20 compared to the scope of claim 73 and the predictability of the art is somewhat higher.
21 Furthermore, the amount of experimentation needed to test operability of a protein of
22 amino acid sequence of SEQ ID NO: 4 is very small and such experimentation is very

1 well guided by the specification; e.g. the nucleic acid encoding this amino acid
2 sequence can be encompasses fewer embodiments compared to the scope of claim 61.
3 Appellant further argues that the specification examples 5-8 describe a species within
4 the scope of claim 83, in that a cDNA encoding RFS from broad bean, a leguminous
5 plant, utilizing some of the primers set forth in claim 83, is cloned and demonstrated to
6 encode a protein having RFS activity. Appellant also argues that a second embodiment
7 within claim 83 is described in the examples, in that a cDNA encoding a protein having
8 a degree of sequence identity to SEQ ID NO: 2 sufficient to identify it as a RFS is
9 cloned using some of the primers recited in claim 83 and a nucleic acid from soybean,
10 which is another leguminous plant, and that the experimentation required to
11 demonstrate that nucleic acids within the scope of claim 83 encode an active RFS is
12 slight, and such experimentation is very well guided by the specification. For example,
13 the nucleic acid can be substituted for that encoding SEQ ID NO: 2 as described by the
14 working example 8. See the paragraph spanning pages 29-30 of the Appeal Brief.

15 Appellant argues that claim 82 is directed to isolated nucleic acids within the
16 scope of claim 53, in which the nucleic acid of the portion encoding an amino acid
17 sequence is obtained by amplification of a nucleic acid obtained from a leguminous
18 plant utilizing specified primers that hybridize to either SEQ ID NO: 1 or SEQ ID NO: 3,
19 or the complement of these sequences. Appellant argues that the breadth of claim 82
20 encompasses fewer embodiments compared to the scope of claim 53. Appellant further
21 argues that the specification examples 5-8 closely describe a species within the scope
22 of claim 82, in that a cDNA encoding RFS from broad bean, a leguminous plant, utilizing

1 some of the primers set forth in claim 82, is cloned and demonstrated to encode a
2 protein having RFS activity, and that a second embodiment within claim 82 is described
3 in the examples, in that a cDNA encoding a protein having a degree of sequence
4 identity to SEQ ID NO: 2 sufficient to identify it as a RFS (SEQ ID NO: 4) is cloned using
5 some of the primers recited in claim 82 and a nucleic acid from soybean, which is
6 another leguminous plant. Appellant argues that the experimentation required to
7 demonstrate nucleic acids within the scope of claim 82 encode an active RFS is slight,
8 and such experimentation is very well guided by the specification; for example, the
9 nucleic acid can be substituted for that encoding SEQ ID NO: 2 as described by the
10 working example 8. See page 30, 2nd paragraph of the Appeal Brief.

11 Appellant argues that claims 83 and 84 are directed to chimeric genes and
12 plasmids, respectively, within the scope of claims 61 and 66, in which the nucleic acid of
13 the portion encoding an amino acid sequence is obtained by amplification of a nucleic
14 acid obtained from a leguminous plant utilizing specified primers that hybridize to either
15 SEQ ID NO: 1 or SEQ ID NO: 3, or the complement of these sequences. Thus, the
16 breadth of claim 83 encompasses fewer embodiments compared to the scope of claim
17 61. Appellant further argues that the specification examples 5-8 describe a species
18 within the scope of claim 83, in that a cDNA encoding RFS from broad bean, a
19 leguminous plant, utilizing some of the primers set forth in claim 83, is cloned and
20 demonstrated to encode a protein having RFS activity. Appellant also argues that a
21 second embodiment within claim 83 is described in the examples, in that a cDNA
22 encoding a protein having a degree of sequence identity to SEQ ID NO: 2 sufficient to

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1 identify it as a RFS is cloned using some of the primers recited in claim 83 and a nucleic
2 acid from soybean, which is another leguminous plant. The experimentation required to
3 demonstrate that nucleic acids within the scope of claim 83 encode an active RFS is
4 slight, and such experimentation is very well guided by the specification. For example,
5 the nucleic acid can be substituted for that encoding SEQ ID NO: 2 as described by the
6 working example 8. See pages 30-31 of the Appeal Brief.

7 Appellant argues that claim 85 is directed to a method for metabolic modification
8 within the scope of claim 74, in which nucleic acids are used that are obtained by
9 amplification of a nucleic acid obtained from a leguminous plant utilizing specified
10 primers that hybridize to either SEQ ID NO: 1 or SEQ ID NO: 3, or the complement of
11 these sequences, thus the breadth of claim 85 encompasses fewer embodiments
12 compared to the scope of claim 74. Appellant further argues that the specification
13 examples 5-8 describe a species within the scope of claim 85, in that a cDNA encoding
14 RFS from broad bean, a leguminous plant, utilizing some of the primers set forth in
15 claim 85, is cloned and demonstrated to encode a protein having RFS activity, and that
16 a second embodiment within claim 85 is described in the examples, in that a cDNA
17 encoding a protein having a degree of sequence identity to SEQ ID NO: 2 sufficient to
18 identify it as a RFS is cloned using some of the primers recited in claim 85 and a nucleic
19 acid from soybean, which is another leguminous plant. Appellant argues that the
20 experimentation required to demonstrate a nucleic acid within the scope of claim 85
21 encodes an active RFS is slight, and such experimentation is very well guided by the
22 specification, for example the nucleic acid can be substituted for that encoding SEQ ID

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1 NO: 2 as described by the working example 8. See page 32, 2nd paragraph of the
2 Appeal Brief.

3 Appellant argues that claim 86 is directed to isolated nucleic acids within the
4 scope of claim 77, in which nucleic acids are used that are obtained by amplification of
5 a nucleic acid obtained from a leguminous plant utilizing specified primers that hybridize
6 to either SEQ ID NO: 1 or SEQ ID NO: 3, or the complement of these sequences. thus
7 the breadth of claim 86 encompasses fewer embodiments compared to the scope of
8 claim 77. Appellant further argues that the specification examples 5-8 describe a
9 species within the scope of claim 86, in that a cDNA encoding RFS from broad bean, a
10 leguminous plant, utilizing some of the primers set forth in claim 86, is cloned and
11 demonstrated to encode a protein having RFS activity. Appellant argues that a second
12 embodiment within claim 86 is described in the examples, in that a cDNA encoding a
13 protein having a degree of sequence identity to SEQ ID NO: 2 sufficient to identify it as
14 a RFS is cloned using some of the primers recited in claim 86 and a nucleic acid from
15 soybean, which is another leguminous plant, and that the experimentation required to
16 demonstrate a nucleic acid within the scope of claim 86 encodes an active RFS is slight,
17 and such experimentation is very well guided by the specification. For example, the
18 nucleic acid can be substituted for that encoding SEQ ID NO: 2 as described by the
19 working example 8. See the paragraph spanning pages 32-33 of the Appeal Brief.

20 These arguments are not found to be persuasive. Because the claimed chimeric
21 gene comprises the isolated nucleic acid of claims 52-58, claims 59-62 lack enablement
22 for the same reasons. The application only teaches one isolated nucleic acid encoding a

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1 raffinose synthase enzyme, in addition to one functionally uncharacterized coding
2 sequence and two partial coding sequences of unknown function. Only one species of
3 the four recited in claim 78, for example, are enabled for the claimed invention. In the
4 same manner, the plasmid of claims 65 and 66, the transformant and host organism of
5 claims 63, 64 and 67-72, and the metabolic transformation aspect of claim 73 or 74 lack
6 enablement because they comprise nucleic acids that have not been fully enabled. The
7 Examiner has not argued that the promoter aspect lacks enablement, just the nucleotide
8 sequence coding for an amino acid sequence of a raffinose synthase as broadly
9 claimed lacks enablement.

Double Patenting

11 Claims 46, 47, 52, 53, 55 and 59-77 and 78-86 stand provisionally rejected under
12 the judicially created doctrine of obviousness-type double patenting as being
13 unpatentable over claims 1-3, 16-23 and 28-30 of copending Application No.
14 09/301,766. Applicants do not address this rejection in the Appeal Brief.

(11) Related Proceeding(s) Appendix

16 No decision rendered by a court or the Board is identified by the examiner in the
17 Related Appeals and Interferences section of this examiner's answer.

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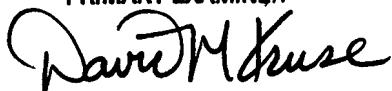
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2 For the above reasons, it is believed that the rejections should be sustained.

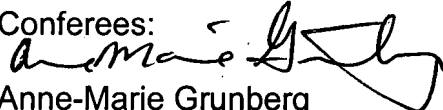
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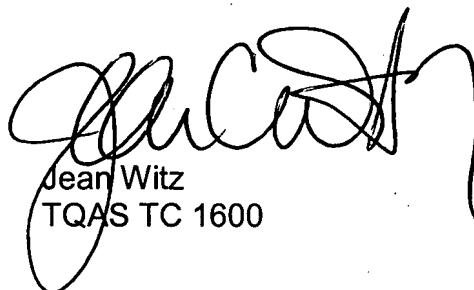
4 Respectfully submitted,

5 David H Kruse
6 Primary Examiner
7 Art Unit 1638
8 **DAVID H. KRUSE, PH.D.**
9 **PRIMARY EXAMINER**



10

11 Conferees:
12 
13 Anne-Marie Grunberg
14 Supervisory Patent Examiner
Art Unit 1638


Jean Witz
TQAS TC 1600